

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

	I hereby certify that this correspondence is being deposited	1
In re patent of:	) with the United States Postal Service as first class mail in an	
Thomas Zdeblick et al.	envelope addressed to Mail Stop: Patent Ext., Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on August 11, 2004.	N N Table 1 Mars
U.S. Patent No. 5,782,919	Christopher A. Brown Name Registered Representative	1 9 2004
Issued: November 16, 1999	Unrespondent Att Jen	OF PETITIONS
INTERBODY FUSION DEVICE AND METHOD FOR RESTORATION OF	August 11, 2004 Date of Signature	>.   . ₩ (AQ)
NORMAL SPINAL ANATOMY	λuguet 11 2004	<del></del>

## <u>COMMUNICATION REGARDING</u> APPLICATION FOR EXTENSION OF PATENT TERM OF U.S. PATENT NO. 5,782,919

Mail Stop Patent Ext. Assistant Commissioner for Patents Post Office Box 1450 Alexandria, VA 22313-1450

Sir:

We have recently reviewed the above-identified application to extend the term of U.S. Patent No. 5,782,919 (the "'919 patent"). In that review, it appeared possible that the length of the requested extension could be misunderstood due to the existence of a terminal disclaimer applied to the '919 patent. With this paper, we want to clarify and re-emphasize that the above-identified application requests an extension to and including July 2, 2016.

Paragraph (11) of the above-identified application requests an extension to and including July 2, 2016, which is the date 14 years from the date of approval of this product. A copy of the terminal disclaimer filed during prosecution of the '919 patent was included with the above-identified application, as indicated in paragraph (7). That terminal disclaimer limits the term of the '919 patent to that of U.S. Patent No. 5,669,909 (the "'909 patent"), i.e. March 30, 2015, assuming the '909 patent remains valid and in force.

The expiration date of the '919 patent given in the above-identified application (see paragraphs (5) and (11)) was 17 years from the issuance of the '919 patent, i.e. July 21, 2015. This date was chosen COMMUNICATION REGARDING APPLICATION FOR EXTENSION OF PATENT TERM OF U.S. PATENT NO. 5,782,919 Atty. Ref.: 4002-209

Page 1 of 2

because that full term might be realized if the '909 patent did not live out the full extent of its term. It is observed that although the terminal disclaimer was acknowledged and provided in the above-identified application, a full discussion of the term extension calculation based on the possibility of a March 30, 2015 expiration date was not supplied.

The expiration date of the '919 patent after the requested extension, i.e. July 2, 2016, is accurate regardless of whether the extension is calculated from March 30, 2015 or from July 21, 2015. This is because, as shown in paragraph (11) of the application, the patent would be entitled to an extension of more than 1200 days based on the regulatory review period. However, by statute no patent can be extended beyond the date 14 years from the regulatory approval date, which is July 2, 2016 in this case. That date is 347 days from July 21, 2015 (see paragraph (11) of the above-identified application), and it is 460 days from March 30, 2015 (compare to the calculation in paragraph (11) of the application to extend U.S. Patent No. 5,984,967 based on the LT Cage<sup>TM</sup>/InFUSE<sup>TM</sup> Bone Graft Product, filed August 20, 2002). Thus, regardless of the day on which the extension begins, this patent is entitled to a term extension to and including July 2, 2016.

Accordingly, assuming the PTO decides to issue an extension of the '919 patent, the PTO is respectfully requested to identify the extension as extending to and including July 2, 2016. If the PTO has any questions or needs further information concerning this matter, it is invited to contact the undersigned attorney.

We look forward to an official communication from the PTO indicating allowance of the requested extension.

Respectfully submitted,

Christopher A. Brown, Reg. No. 41,642

Woodard, Emhardt, Naughton, Moriarty & McNett

Bank One Center Tower

111 Monument Circle, Suite 3700

Indianapolis, Indiana 46204-5137

(317) 634-3456